DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

D1246B 3/14/97
HFI-35

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-30

March 7, 1997

Mr. William G. Coll
Chairman of the Board/President
Separation Technology, Inc.
1096 Rainer Drive
Altamonte Springs, FL 32714

Dear Mr. Coll:

During an inspection of your facility, in Altamonte Springs, Florida on February 25 & 27, 1997, FDA Investigator Ronald T. Weber determined that you manufacture and distribute microhematocrit centrifuges which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the devices are adulterated within the meaning of section **501(h)** of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the Current Medical Device Good Manufacturing Practices as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to the following.

1. Failure to conduct planned and periodic internal audits of the quality assurance program in accordance with written procedures [21 CFR 820.20(b)], e.g., there has not been an internal audit conducted since 3/17/94.

2. Failure to identify, recommend or provide solutions for quality assurance problems and verifying the implementation of such solutions [21 CFR 820.20(a)(3)], e.g., a significant failure trend concerning 60% to 80% failure rates of the motors in the microhematocrit centrifuges was identified in April of 1996 and there is no assurance this failure mode has been corrected. Production and distribution of this device continues.

3. Failure to establish and implement an adequate failure investigation program [21 CFR 820.162], e.g., there are no available records of the failure investigation conducted to establish the cause of the failures described above.

4. Failure to document, review, approve, and validate changes to components, finished devices, labeling, packaging or manufacturing process specifications [21 CFR 820.100(b)(1),(2) & (3)], e.g., there is no documentation of the prior approval of the software specification change initiated 1/24/97 that was an attempt to correct the failures described above. Also, there is no change validation to assure the software modifications will correct the failure mode.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483, Inspectional Observations, issued to you, during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMAs) or export approval requests will be approved and no premarket notifications [510(k)s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including (1) each step that has or will be taken to correct the current violations, (2) the timeframe within

which the corrections will be completed, (3) the person responsible for effecting correction, and (4) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Please direct your reply to Timothy J. Couzins, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone number (407) 648-6823, Ext. #264.

Sincerely,

Douglas D. Tolen
Director
Florida District